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Dated 25 September 2003

Patents Form 1/77

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P01/7700 0.00-0219944.6

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Request for grant of a patent

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28 AUG 2002

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1. Your reference
SR/MR/OGM.3

2. Patent application number
(The Patent Office will fill in this part)
0219944.6

3. Full name, address and postcode of the or of each applicant *(underline all surnames)*
Owen Greenings & Mumford Limited
Stanton Harcourt Road
Eynsham
Oxford OX29 4JB

Patents ADP number *(if you know it)*
8295834001

If the applicant is a corporate body, give the country/state of its incorporation
United Kingdom

4. Title of the invention
Urine Collection Device

5. Name of your agent *(if you have one)*
WYNNE-JONES, LAINE & JAMES

"Address for service" in the United Kingdom to which all correspondence should be sent *(including the postcode)*
22 Rodney Road
Cheltenham
Gloucestershire GL50 1JJ

Patents ADP number *(if you know it)*
1792001 ✓

6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and *(if you know it)* the or each application number

Country	Priority application number *(if you know it)*	Date of filing *(day / month / year)*
—		

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Number of earlier application	Date of filing *(day / month / year)*
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8. Is a statement of inventorship and of right to grant of a patent required in support of this request? *(Answer 'Yes' if:*
a) any applicant named in part 3 is not an inventor, or
b) there is an inventor who is not named as an applicant, or
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Patents Form 1/77

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Claim(s)	–
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Priority documents	–
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Statement of inventorship and right to grant of a patent *(Patents Form 7/77)*	–
Request for preliminary examination and search *(Patents Form 9/77)*	–
Request for substantive examination *(Patents Form 10/77)*	–
Any other documents *(please specify)*	–

11. X We request the grant of a patent on the basis of this application.

Signature Wynne-Jones Lainé & James Date 28 Aug 2002

12. Name and daytime telephone number of person to contact in the United Kingdom SUSAN RATCLIFFE – 01242 515807

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URINE COLLECTION DEVICE

This invention relates to a urine collection device and in particular but not exclusively to a urine collection device for use by females. In particular and again not exclusively, the urine collection device is configured such that it can be connected to a pump and urine can be collected when the user is in a number of positions, including both the supine and reclining position.

Devices for the collection of urine from female patients who are bedridden are known. Such devices often involve catheters that have to be inserted within the urethra of the patient, which in itself can be an uncomfortable procedure. Further, catheters often form a site where bacteria can accumulate which may result in the infection of the urinary tract and possibly the bladder thereby leading to complications in the treatment of an individual.

It is known to use specially shaped funnels, which are shaped to the contours of the female genital region and these collect and conduct urine away from the user's body. Such urinary funnels are disclosed in EP 464575 and WO 90/13280 and GB 2362577. However, some known funnels used in the reclined or supine positions do not form an adequate seal between the user and also "puddling" of urine within the device can occur. Consequently, known urine collection devices are prone to leakage due to the backflow of urine contained that has collected within the device, which has the disadvantage that both the user and bed linen may become soiled by leaked urine. Further, known devices are not designed for use when the patient is in a number of positions for example laying down or sitting in a reclining position.

urine collection device that avoids leakage of urine from the device and which can be used when the user is in a number of positions.

According to a first aspect of the invention, there is provided a urine collection device comprising a funnel having a front wall positionable towards the pubic bone area of the user, side walls being positionable either side of the area of the user's body from which urine is expelled and a bottom wall, positionable towards the rear of the user, the upper edge of the front and forward parts of the side walls forming an opening for the funnel which extends around the area of the user's body from which urine is expelled, the funnel also having an outlet by which urine can be removed from the urine collection device, wherein the opening for the funnel leads to a urine receiving area formed by the front wall and forward parts of the side walls of the urine collection device, said urine receiving area leading to a urine collection reservoir formed of the bottom wall and rearward parts of the side walls of the urine collection device, said urine collection reservoir having a back wall extending from the opening of the funnel in the vicinity of the perineum of the user towards the bottom wall so that the urine collection reservoir is provided as a substantially closed chamber, which receives urine indirectly from the user via the urine receiving area, said urine collection reservoir leading to the outlet so that urine can be removed from the funnel.

Preferably, the opening of the funnel is contoured such that it is generally has an arcuate shape with front part and rear parts of the opening being raised in comparison with the side walls of the opening, said raised parts forming a two point axis of contact with the user's body. The whole of the circumference of the

opening is in contact with the user's body but the two point axis defines a line in the x-x axis of contact with the user.

It is desirable that the opening of the funnel includes a lip curling towards the inside of the funnel. This lip forms a gutter that assists in directing urine towards the urine-collection reservoir.

Preferably, the lip has an irregular profile with there being a greater degree of lip at the front part of the opening than at the rear part of the opening.

Ideally, there is no lip towards the rear of the opening in proximity to the perineum. By having the lipped graduated gutter arrangement, urine generally flowing through the device, i.e. urine which is not being propelled into the receiving area is caused to be deflected back into the device and downwards so it is directed towards the collection reservoir and the outlet end, thereby avoiding leakage. It may be that the lip of the device is formed of a softer material than the main body of the device so that there is some give in the lip to allow deformation to form a seal with the body of the user.

In a preferred arrangement, the back wall of the urine collection reservoir is sloped away from the two-point axis of contact, in a direction away from the user's body.

Advantageously, the back wall is at an angle of between 120 degrees and 160 degrees and more preferably at an angle of 130-150 degrees from a plane formed by two-point axis.

Ideally, the back wall is at an angle of 146 degrees from a plane formed by the two-point axis of contact.

It is preferred that the bottom wall of the urine collection device is at an

angle of 106 degrees from the back wall of the device but this angle may vary by fifteen degrees either side of this value.

Advantageously, the outlet has an opening leading from the urine collection reservoir, which is positioned such that said opening is directed towards an area of the device where the back wall and the bottom wall of the urine collection reservoir meet. The outlet may be formed as a tube within the body of the device with a wall of the tube merging into the bottom wall of the urine collection device. The use of a tube within the urine collection device itself to form the outlet allows for a weir to be formed so that urine in the collection reservoir is directed to flow towards the opening for the outlet. This allows for controlled flow of urine from the device without splashing or back flow of urine to the opening for the device.

It is envisaged the urine collection device includes one or more weirs on inner sidewalls of the funnel to control flow of urine within said device.

Preferably, at least one of the weirs is positioned before the opening of the outlet leading from the device.

It is also envisaged that there may be weirs in proximity to the opening of the urine collection device, said weirs being in contact with the patient's body so that urine may be more efficiently directed towards the inner surface of the funnel. The use of said weirs has the advantage that they assist in directing the flow of urine from the patient into the body of the urine collection device.

Preferably, the weirs each have a curved surface. By having a curved surface, this assists in preventing the weirs from being deflected counter to the flow of urine due to the pressure of urine within the device. If deflection is

avoided, there is a reduction in splashing of urine. This assists in encouraging cross flow of urine back into the body of the device and prevents any downward flow of urine from the device to the perineum and ultimately down the legs of the user and possibly onto the nursing staff

It is preferred that the outlet for the funnel can be connected to a tube of around 8 millimetres in order to direct urine from the funnel at a flow rate of 60 millilitres per second.

Preferably the capacity of the collection reservoir of the funnel needs to be at least 20 millilitres position when in a supine position to avoid the risk of leakage.

Advantageously, the front wall of the funnel, which forms the front part of the urine-receiving reservoir, is provided as a smooth concave contour so that urine is deflected towards the urine collection reservoir and then to the outlet. The concave surface acts as a deflector for a urine stream and so the flow is controlled so that it may be directed over the surfaces of any weir present and into the body of the reservoir. The curved surfaces of the weir also aid in controlling flow thereby reducing the risk of leakage or splash back of urine. Also, by having a concave front face, there is the avoidance of turbulence, which could create a fluid/air mix that will reduce the effectiveness of drainage from the funnel.

Preferably the urine collection device has a hand locating area on the walls of the device forming the urine receiving area. The locating area is provided by visual or tactile areas that the user can locate so that they know when they are holding the urine collection device in the most appropriate

orientation for use whereby the user's hand is directed to be applied in the correct plane to pull the part of the device which contacts on the perineum into that area thereby avoiding having a gap between the urine collection device and the user.

It is envisaged that the funnel may include air apertures. Preferably, the apertures are in the walls of the part of the device forming the urine-receiving reservoir. It is envisaged that the apertures are valved. The valved arrangement allows for pressure within the urine collection device may be regulated if urine is being removed from the device using a pump. Preferably the valves are self-regulating in that when a certain negative pressure is reached within the device, then the valves are caused to operate. The valves operate by allowing air into the urine collection device before urination and this also stops negative pressure from the pump building up, which may harm a user. As urination occurs, which may be detected by a sensor within the valve or the body of the device, the valve or valves are caused to close so that leakage from the device is prevented. The change over from negative to atmospheric pressure causes the valves to operate. Also negative pressure can build up so that urine can be removed from the device.

The positioning of the angle of the walls of the various parts of the urine collection part are important in that by having walls that have defined angles relative to one another and curved surfaces, urine is caused to flow through the device at an optimum rate whilst avoiding excessive turbulence that could disrupt the flow dynamics of the urine within the device.

Further, by having an outlet that is offset from the opening of the funnel,

urine flow is fed to the outlet in a controlled manner rather then being able to directly reach the outlet as in known devices. Urine is allowed to pool at the lowest point of the urine collection, which is formed by the urine collection reservoir, thereby leading urine to the mouth of the outlet part so that urine can be sucked away. Further, by having a series of angles for the urine collection device, the device can be used when the patient is both in the sitting and supine positions. This is because the back face and bottom face are at an angle so that urine is constantly being removed from the device at peak flow rates, via the outlet a peak flow rate being typically 60 millilitres per second, whilst at the same time avoiding leakage.

According to a second aspect of the invention, there is provided a urine collection arrangement comprising a funnel having a front wall positionable towards the pubic bone area of the user, side walls being positionable either side of the of the area of the user's body from which urine is expelled and a rear wall, positionable towards the perineum area of the user, the upper edge of the front and forward parts of the side walls forming an opening for the funnel which extends around the area of the user's body from which urine is expelled, the funnel also having an outlet by which urine can be removed from the urine collection device, wherein the opening for the funnel leads to a urine receiving area formed by the front wall and forward parts of the side walls of the urine collection device, said urine receiving area leading to a urine collection reservoir formed of the rear wall and rearward parts of the side walls of the urine collection device, said urine collection reservoir having an upper wall extending from the opening of the funnel towards the rear wall so that the urine collection

reservoir is provided as a substantially closed chamber which receives urine indirectly from the user via the urine receiving reservoir, said urine collection reservoir leading to the outlet so that urine can be removed from the funnel, the outlet being connected to a tube leading to a pump whereby urine from the urine collection device is pumped to a urine collection chamber.

Preferably the funnel includes a weir to prevent or inhibit backflow of urine away from the direction of suction.

Conveniently, a valve is incorporated within the apparatus such that urine exiting from the funnel cannot flow back under gravity when the suction pump is deactivated.

It is envisaged that the pump is a linear diaphragm pump. Linear diaphragm pumps have the advantage that they can achieve high flow rates required to meet the instantaneous flow rate that occurs when a person is urinating, with the added advantage of being small, light weight and easily portable and also being relatively quiet.

Advantageously, the pump is a compressor that is self limiting in terms of negative pressure that can be produced. This provides an inherent safety feature in that it avoids the production of unsafe vacuum which can harm the user of the urine collection device.

Advantageously, the pump includes a silencer and/or a carbon filter to reduce odours

Typically, the suction pump leads to a collection vessel which is a sealed airtight vessel, which can be depressurised by the compressor to a negative of –270 millabars.

It is preferred that the pump includes a check program to ensure correct operation and connection of the pump to the urine collection device and/or the urine collection chamber. The check program may be preceded by an indication of whether the pump is on or off and this can be provided by a visual indication on a display or an audible warning. Once the pump is judged to be operating correctly, an indication is given to the user that they can start using the pump with the urine collection device.

Preferably, a test program is provided which prompt the user to check that the arrangement is operating properly after the pump is switched off. An example of this is where the pump has been switched off to empty the urine collection chamber. An indicator is activated after the chamber has been emptied to prompt the user to run the check program again. The test program is controlled as a result of receiving signals from various parts of the pump arrangement. A sensor may be associated with the container to check that it has been properly connected to tubing associated with the pump.

Further tubing leading to and from the pump can also include sensors at one or more points to receive information about blockages or power leaks in the pump system.

It is preferred that pressure checks are performed by the pump being caused to evacuate the pump arrangement to set a negative pressure and a check is made to see if this pressure is reached and held for a predefined period of time. If the check result is a negative result, the user will be prompted to check the system to ensure that tubing and connections between the tubing and components such as the container for the urine are secure.

Advantageously there is a hydrophobic filter membrane between the collection vessel and the pump to prevent any potential ingress of urine in to the pump, which could have major health and safety implications. Further, the filter membrane assists in preventing ingress of bacteria.

It is envisaged that the collecting vessel may be calibrated to measure the amount of urine that the patient is releasing so that flow rates of fluid through the body can be monitored.

Advantageously, the collection chamber includes a disposable bag having a tap at the bottom for emptying contents from the bag. This allows the bag to be used for a user a number of times, much like catheter bags, which are periodically drained. In a preferred arrangement, the collection chamber is associated with a sensor which can provide a signal for an indicator to inform a user when the bag within the collection chamber is full or has reached a certain fill limit. Further, the collection chamber may have a sensor that can calibrate the flow rate of urine over a particular period of time to monitor whether a patient is producing urine at an appropriate amount relative to their fluid intake. By measuring flow rates conditions such as oedema or urinary blockages may be detected.

In a preferred arrangement, the pump is provided as a portable device. It is envisaged that when the pump is portable, said pump is provided as a separate unit attachable to a docking station that can also accommodate the urine collection chamber. It is envisaged that the docking station is connectable to an external power source such as the mains electricity supply. However the pump may include its own integral power supply such as a rechargeable battery

pack.

According to a third aspect of the invention there is provided a urine collection apparatus comprising a funnel for receiving urine, a pump arrangement for pumping urine form the funnel and a collection device for receiving collected urine, said funnel having an outlet which is connected to tubing leading to the pump arrangement, wherein the pump arrangement includes sensors to detect parameters concerning itself, the tubing and the collection device and indicators to alert a user of the device whether defined parameters fall within or outside said defined parameters.

It is preferred that the pump arrangement includes a check program to monitor pressure within said urine collection arrangement.

Advantageously, the test program is provided with an indicator that prompts the user to check that the arrangement is switched on. Preferably as well as checking whether the arrangement is switched on, the user is prompted to check that all components are present and connected properly. The check may comprise visual indicators alerting the user of the stages in the check process to be taken. Alternatively, an audible prompt may be used to talk the user through the various stages in the check procedure.

Preferably, the check program includes means to indicate when the collection chamber has been detected as having been emptied, then the user should run the check program again. The test program is controlled as a result of receiving signals from various parts of the pump arrangement. A sensor may be associated with the container to check that it has been properly connected to tubing associated with the pump. Further tubing can also include sensors at one

or more points to receive information about blockages or power leaks in the pump system.

It is preferred that pressure checks are performed by the pump being caused to evacuate the pump arrangement to set a negative pressure and a check is made to see if this pressure is reached and held for a predefined period of time. If the check results in a negative result being shown, the user will be prompted to check the system to ensure that tubing and connections between the tubing and components such as the container for the urine are secure.

Preferably, the pump is provided as a portable device, which can be docked with a base station adapted to receive said pump and a urine collection chamber.

It is envisaged that the pump includes its own power supply or it can be connected to a power supply provided by the base station.

The invention will now be described, by way of example only, with reference to the accompanying figures in which:

Figure 1 shows the urine collection device according to the first aspect of the invention,

Figure 2a shows a urine collection device according to the invention in situ with the body if a user,

Figure 2b shows a front perspective view of the urine collection device according to a first aspect of the invention,

Figure 3a shows the angle of a urine collection device according to a first aspect, when a user is in a reclined sitting position,

Figure 3b shows the angle of use of a urine collection device according to

a first aspect, when a user is in a supine position,

Figure 4a shows weirs positioned on the inside of the urine collection device according to an embodiment of the invention,

Figure 4b shows a view from above of the urine collection device including weirs,

Figure 5 shows suction pump to be used with a urine collection device according to the first aspect of the invention, and

Figure 6 shows a portable pump to be used with a urine collection device according to an embodiment of the invention.

The urine collection device generally shown as 1 comprises a funnel body 2 having an upper edge 3 providing an opening for the funnel. Upper edge 3 has front contact point F, which contacts with the pubic bone area of the user and a rear contact point R that contacts with the perineum area of the user. Between the front region F and the rear region R there is a region U, which is typically the area of the urine collection device 1 which is in proximity to the area of the user's body surrounding the urethra. The funnel body 2 has a contoured outer front face 7 leading from contact point F to form a bowed concave area 8, which is the typical region as a user holds the urine collection device. The area forms the urine receiving area of the urine collection device and is the part of the device where the urine directly enters the device via the opening 3. The front curved area 7 leading to 8 forms a contoured "S" curve leading towards outlet tube 9. The outlet tube 9 leads from an extension of the urine collection device 1 which extends from the rear of the opening 3 beyond the plane of contact point R to form the extension that provides a urine collection reservoir 10 for the

device. This urine collection reservoir is provided as a closed chamber that directs urine to the urine collection reservoir prior to it passing to outlet tube 9. The chamber is formed by a back wall 11 and bottom wall 12, which are angled to one another thereby providing the collection chamber with a substantially rectilinear shape to provide the urine collection reservoir 10. Area 3a provides a lip for the opening leading to a weir.

Figure 2a shows urine collection device 1 in situ. The urethra of the patient is shown as U and the front and rear contact points F, R are where the urine collection device contacts with the user's body. Edge 3 will contact with the body. The labia majora 13a will seat outside the walls of the opening 3, forming a seal around the top of the opening. The labia minora 13b will be positioned within the device and can protrude up to 18 mm within the device, the labia minora 13b being bounded by opening 3. The contact points F and R provide an axis running between lines x and x of the user's body. The back wall 11 is steeply angled relative to the axis x-x. Typically this angle is 146 degrees but as mentioned the angle may be 130 - 160 degrees. If the angle is much greater, then the back wall 11 would press against the buttocks of the user making the device difficult to use because it does not seal with the user and also there is the possibility that the device may be knocked from position thereby causing leakage. Back wall 11 is angled relative to bottom wall 12 and the typical angle between these walls is 106 degrees with a range being 90 - 120 degrees. By providing such an angle, a urine collection reservoir is formed such that urine is caused to pool in the lowest part of the urine collection device, whether the user is sitting or lying down. Urine is directed from the urine

receiving area formed by curved face 8 towards the urine collection reservoir 10. This allows the urine to pool so it may be siphoned off rather than being directed back towards the opening 3 where leakage may occur. The opening to the outlet 9 is in proximity to the angle 14, where back wall 11 and bottom wall 12 meet. By having the opening to the outlet positioned in proximity to this angle are, controlled flow of urine from and within the device may be facilitated.

Figure 2b is a perspective view from above of a urine collection device according to the invention showing the opening 3 front part F rear part R and urine collection reservoir 10. It can be seen that the urine collection reservoir is offset from opening 3, rather than being positioned directly under it.

Figures 3a and 3b respectively show the position of the urine collection device when a user is in a reclined sitting position, which is usually when a patient is propped up in bed by several pillows, and when a user is lying down in the supine position. As shown in Figure 3a, when a user is reclining, typically the device is held at 100 degrees to the horizontal.

Figure 3b shows the device when it would be used when a patient is the supine position, when typically, the angle to the horizontal is 125 degrees, which is a much steeper angle than when the user is reclining. However, from both arrangements, it can be seen that the urine collection reservoir 10 is always maintained as the lowest part of the device and it is here that urine is held prior to it being removed through outlet 9.

Figure 4a is a cut away view of the rear part of the urine collecting device having vanes on the internal surface of the device. These vanes provide weirs 15 which are angled such that urine would be directed towards collection point

10 and ultimately to outlet 9.

Figure 4b shows the view from above of the weirs 15 in situ relative to opening 3.

Figure 5 shows a pump that may be used with a urine collection device. This pump may be used with a urine collection device as previously described or with other types of urine collection devices. It is preferred that the pump is a linear diaphragm pump, typically having a specification of 230 volts 50/60 hertz frequency and a maximum pressure of 5.5 psi with a maximum of 50 millimetres hd2 under a 50 millimetres hg is used. Typical maximum power is 27 watts with a free airflow of 40 litres per minute.

A urine collection device 1 is attached to a tube 16, which may have a cap at the end connectable to the urine collection device to close off the tube if needs be. A tube is preferably 8 millimetres in diameter and a typical length of tube is around 1.8 metres. The end of the tube which is attachable to the pump interacts with an airtight seal 18 which controls the flow of urine into a collecting vessel 19. Typically the collection vessel is under negative pressure. The collecting vessel may include a disposable bag 20, which stores urine 21, the collectable bag can have a outlet valve 22 for siphoning off urine when it gets to a particular level. This may be detected by a sensor 23 which typically is a level sensor located adjacent to the collecting vessel and senses when the bag fluid level has reached a predefined level. The pump may include a cut off which will not allow the pump to restart until the bag 20 has been emptied. It is envisaged that the pump housing includes an indicator 24 which can be activated by the sensor to give a audible or visual alarm when the bag needs to be emptied. The

indicator can include an on off switch as well as an indicator to show that the pump 25 is running at required levels. The indicator may also include a prompt for the operator to run a test programme. It is envisaged that if a test programme is not run successfully, the pump cannot be used. The test programme tests that the bag has been changed and that there are no air leaks in the system or blockages which could affect the successful use of the equipment by the user. The test system works by evacuating the system to set a negative pressure and checking that this pressure is reached and maintained. In order to do this, the operator must close a clamp on the tube and then press the test programme button. If the test is successful, indication will be shown on the display 24 which will then prompt the operator to check that the collecting vessel and bag connected correctly and if there is still no operation of the pump, then the user would be prompted to fit another collection bag. In order to reduce odours etc, there is charcoal filter 26 which may be incorporated or provided separately from a silencer. Such arrangements make the device more pleasant to use in that it reduces odour and maintains a quiet environment when the pump is being used.

The arrangement shown in Figure 5 is a one to one arrangement where a single pump is used with an individual urine collection device. Figure 6 shows a portable urine collection device. A tube 16 attachable to a urine collection device 1 and a collection chamber 19 attached to a base 27. This base may be connected by an electrical power source via plug 28. This base provides a base station onto which a portable pump arrangement 29 can be seated. This arrangement has a pump 25 and indicator 24 and a carry handle 30. The pump

arrangement is docked on to the base station and connections are made with tubing for airflow to be sucked through the pump 31. The power supply between the base station and the portable pump is provided by connector point 32. Tests will be made using the indicator panel to ensure that appropriate electrical connections have been made and that urine has been correctly connected so that the device will operate properly.

By providing a portable device that may be transmitted between patients, there is a reduced risk of cross contamination and also a cost consideration that one pump can be provided to treat several patients on a ward. It is envisaged that the portable pump/control unit can also contain a rechargeable battery pack so that the device does not necessarily have to be docked into the main power supply. Further, by having parts that can be interconnected, some parts may be provided as disposable elements that can be replaced easily while other parts of the arrangement can be dismantled for sterilization when needs be.

Although the urine collection device is particularly adapted to be used by females, it is envisaged that the device could be used by males having a short urethra or possibly males that are undergoing gender realignment surgery. It is envisaged that such a device, like the present device will have a collection reservoir formed of substantially closed chamber extending from a region in proximity to the perineum towards the buttocks.

It is to be understood that the above detailed description is an embodiment of the invention and is provided by way of example only. Various details in the design and construction of devices described may be modified without departing from the true spirit and scope of the invention.

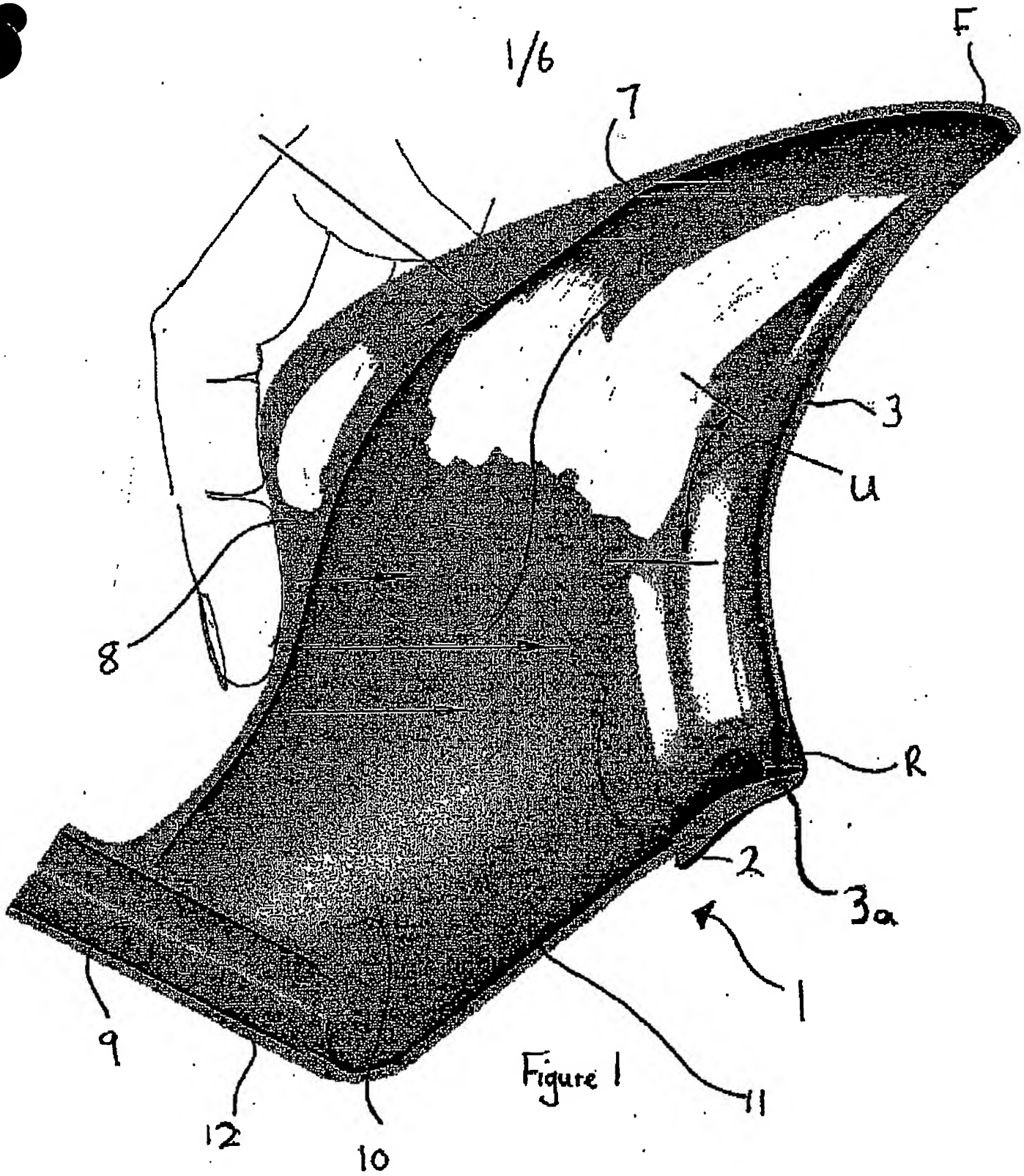

Figure 1

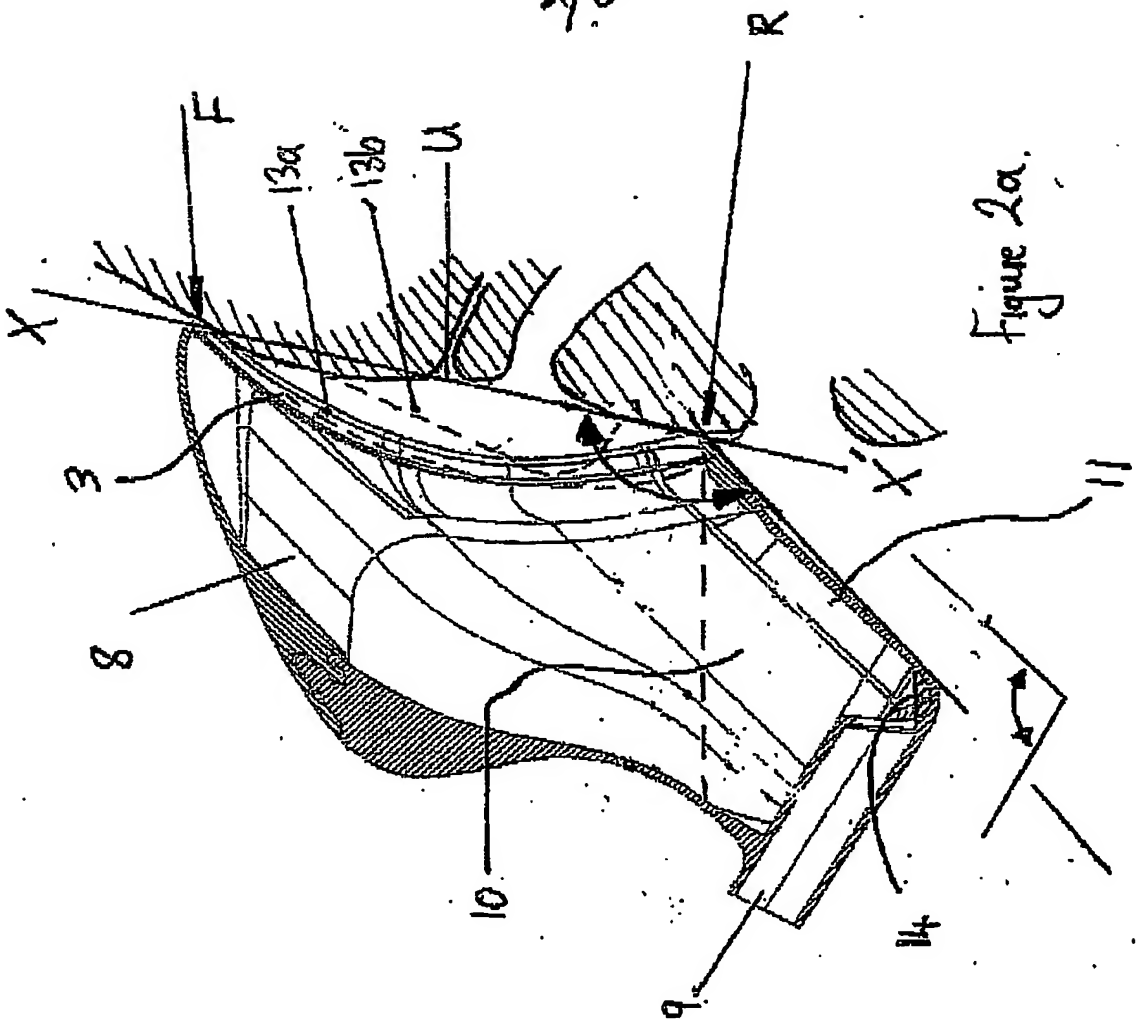

Figure 2a.

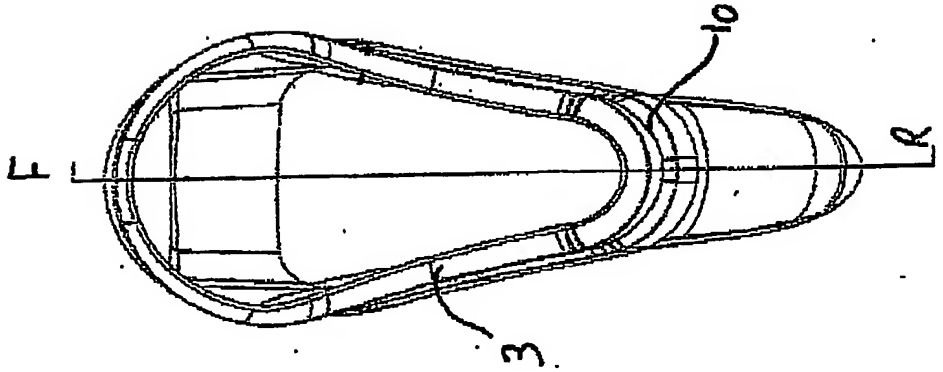

Figure 2b

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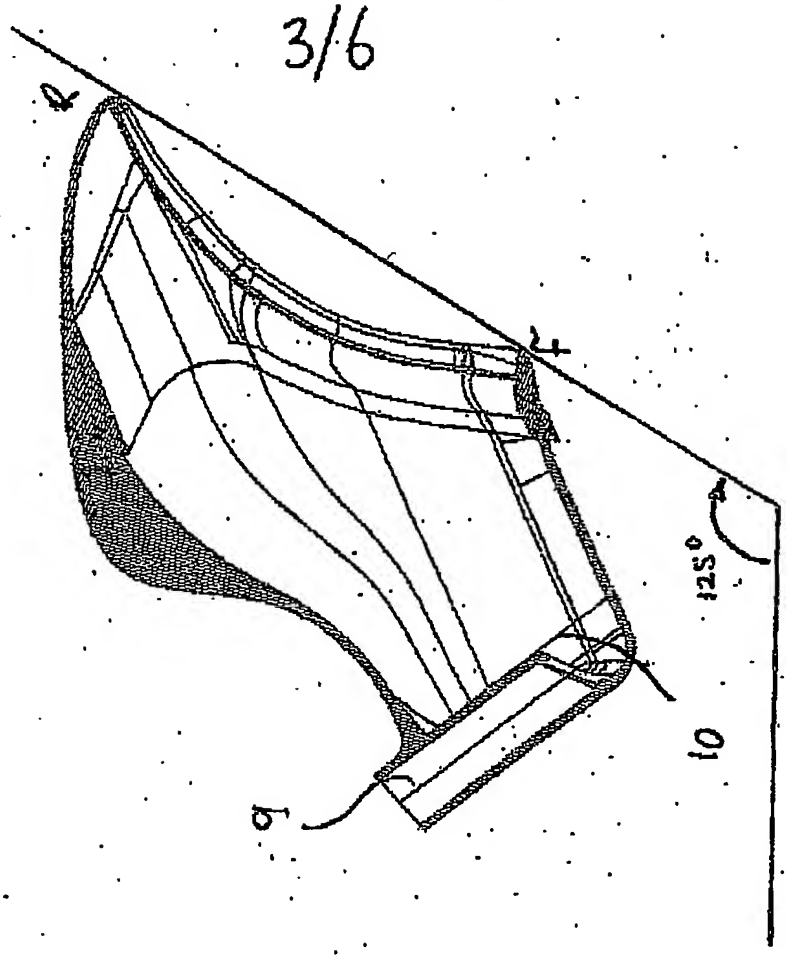

Figure 3b

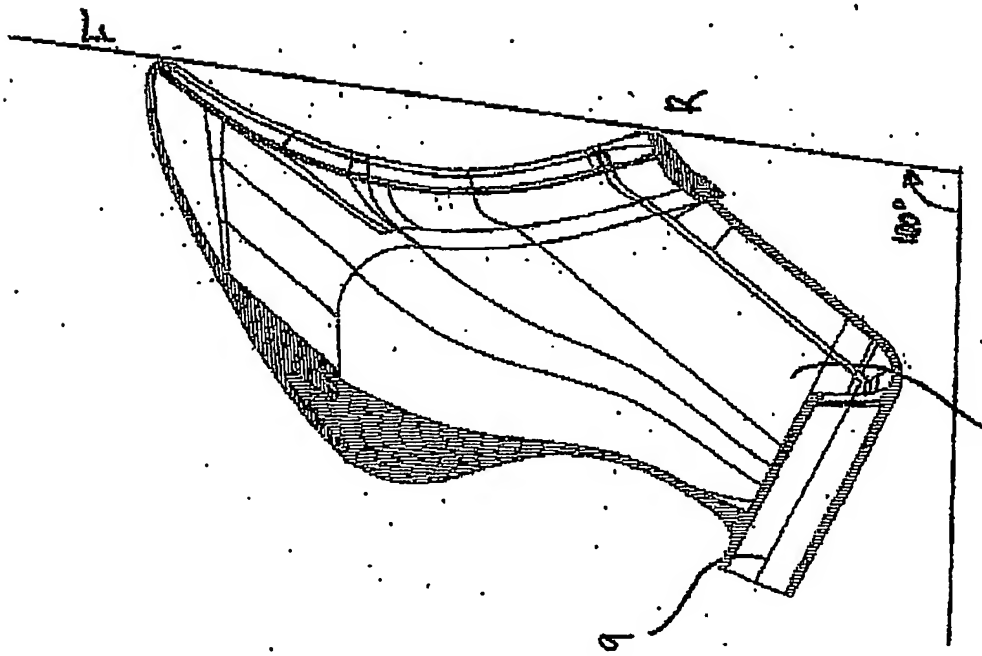

Figure 3a

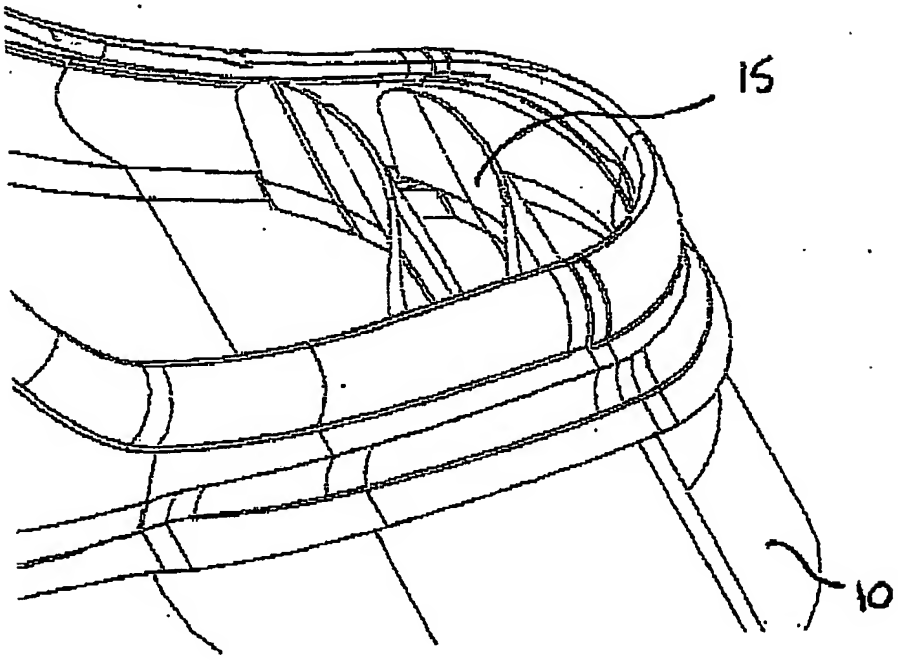

Figure 4a

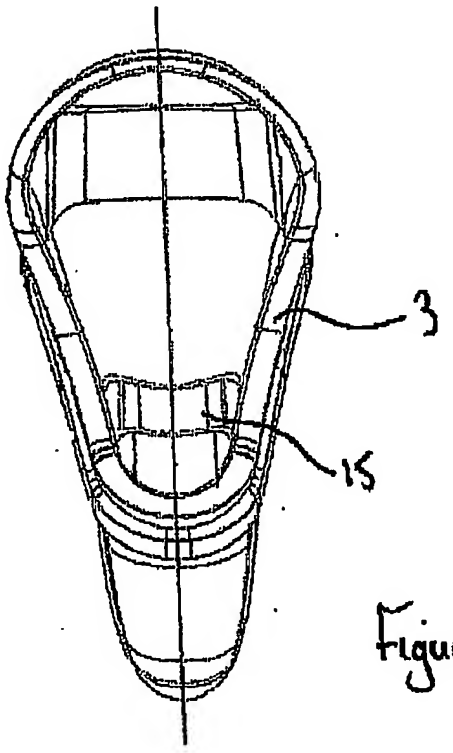

Figure 4b

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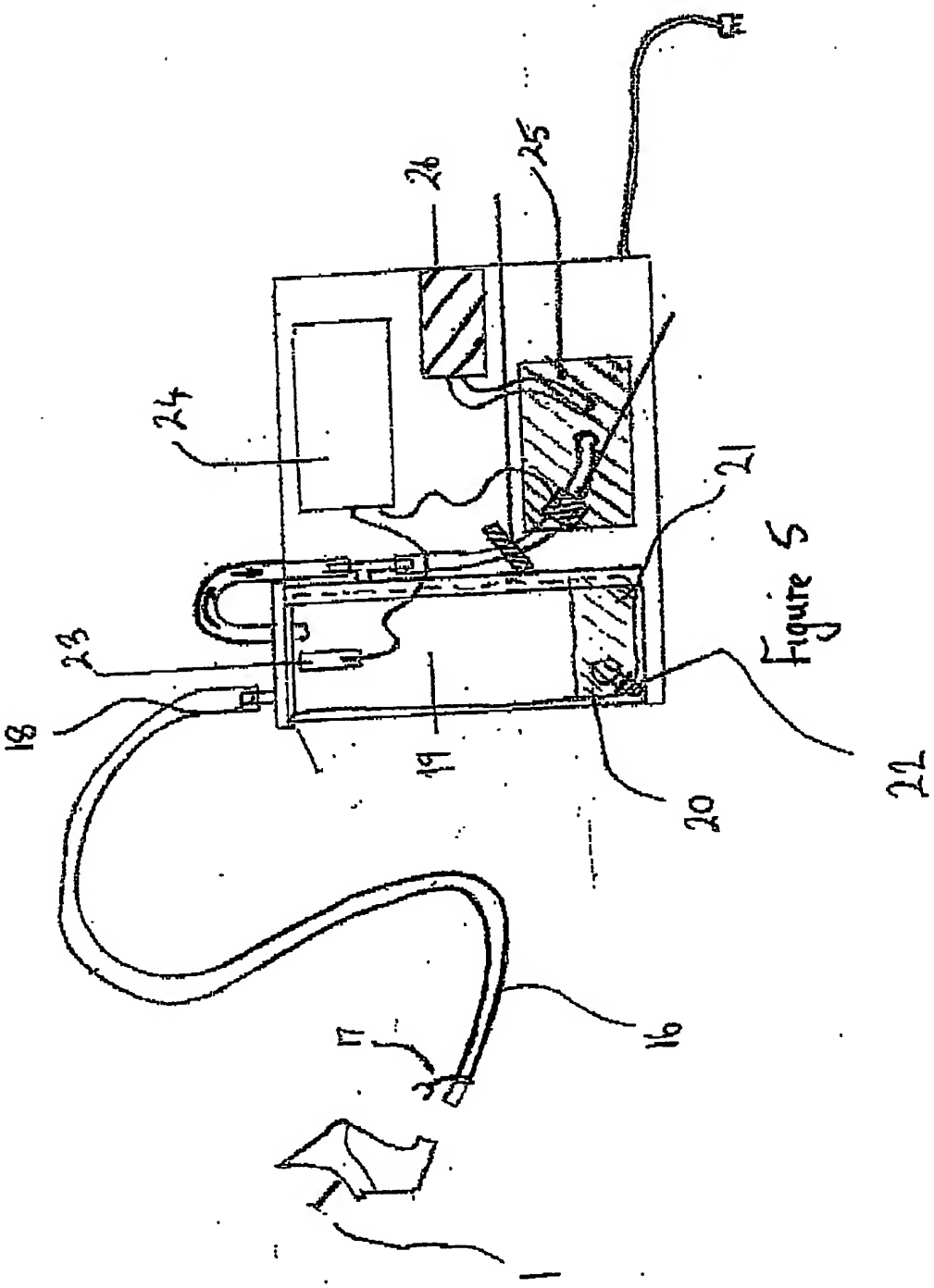

Figure 5

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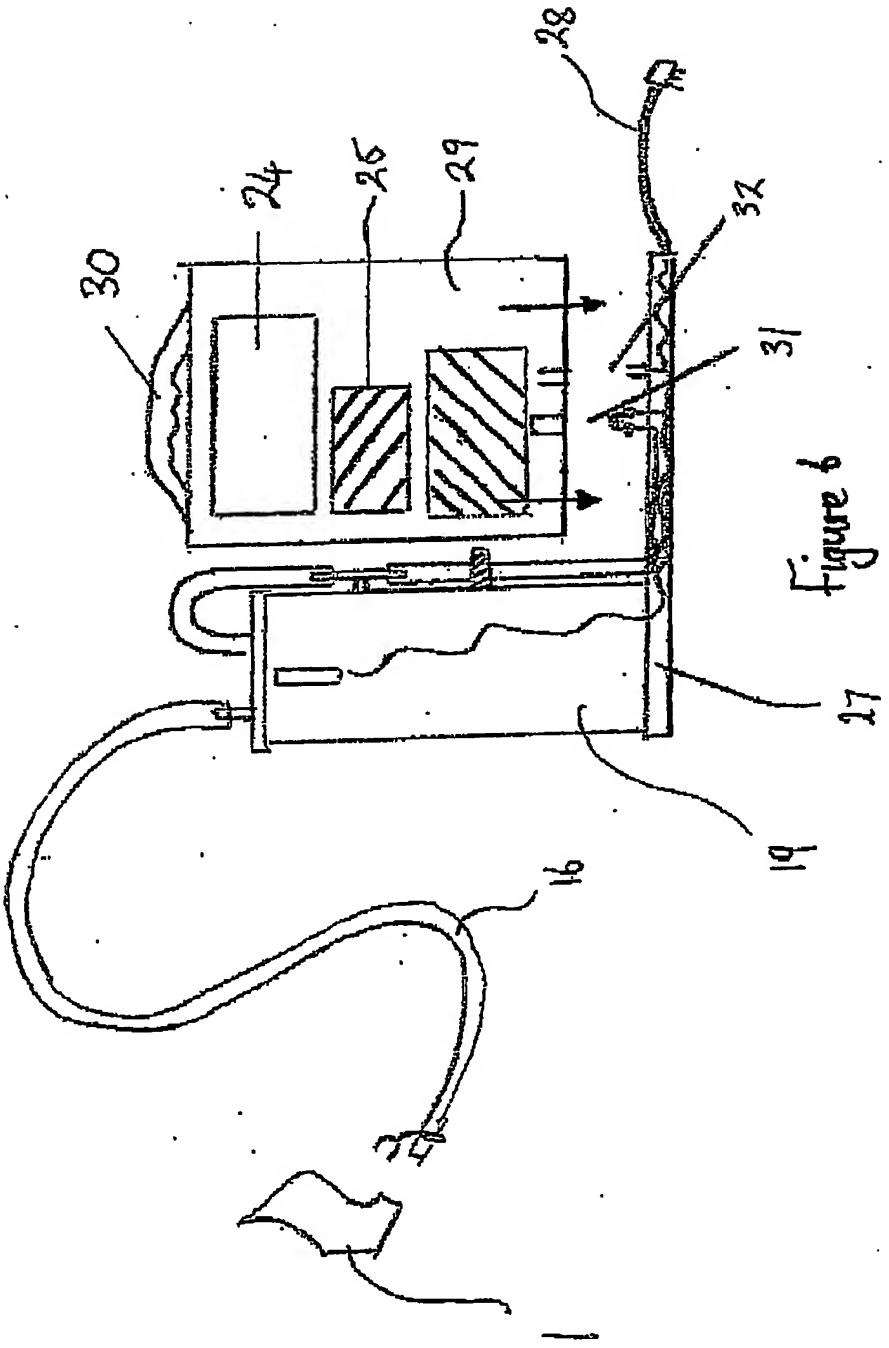
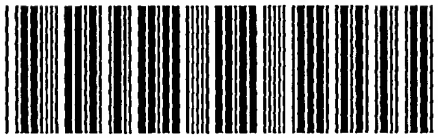


Figure 6



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